UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,975	05/10/2007	Anthony John Clark	9052-241	4577

20792 7590 06/10/2009
MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
SINGH, ANOOP KUMAR	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
06/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,975	CLARK ET AL.	
	Examiner	Art Unit	
	ANOOP SINGH	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27 and 31-40* is/are pending in the application.

4a) Of the above claim(s) *9,10,16-18 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11-15,19-27 and 31-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/22/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response to restriction requirement to the claims filed March 23, 2009 has been entered. Applicants' amendments to the specification and claims filed 3/6/2006 have also been received and entered. Applicants' have amended claims 1-27, 31-33, while claims 28-30 have been cancelled. Applicants have also added claims 34-40 generally directed to elected invention.

Currently, claims 1-27, 31-40 are pending.

Election/Restrictions

Applicant's election with traverse, of claims 1-8, 11-15, 19-20, 26-27, 31-40 (Group II), drawn to a nucleic acid construct comprising a nucleic acid sequence further comprising a nucleic acid sequence encoding a reporter protein that is secreted is a human beta choriogonadotrophin (hCG), a host cell comprising the nucleic acid of the invention and method of using cell for in vitro screening is acknowledged. The traversal is on the grounds that it would not require additional search to examine claim 21-25 as they relate to nonhuman animal and hCG and also they form a single inventive concept. Such is not persuasive, as previous office action clearly states that the "special technical feature" linking the invention of group I-VI is a nucleic acid encoding a reporter gene that is secretable or excretable as a protein. It was clearly indicated this special technical feature does not contribute over prior art as evident from the teaching of Jain et al (J Biol Chem. 2000; 275(35):27032-6, IDS) and also evident from Matzuk et al (Biology of Reproduction vol.69, no. 1, 2003, 2003, pages 338-346). Additionally, it is noted that invention of group IV (claims 21-25) is directed to distinct product, which comprises the use of the nucleic acid "special technical feature" in order to achieve its respective and intended objective. However, for the sake of compact prosecution, claims 21-25 (group VI) directed to transgenic mouse comprising a nucleic acid sequence encoding a reporter protein that is secreted is a modified human beta choriogonadotrophin (hCG) are rejoined with the elected invention of claims 1-8, 11-15, 19-20, 26-27, 31-39 (group II). Additionally, it is noted that claim 40 reads on non elected reporter protein that was inadvertently included in invention of group II.

Therefore, claim 40 is withdrawn from the elected group. The requirement for restriction is deemed proper, maintained and herby made FINAL.

Claim 9-10, 16-18, 40 directed to a nucleic acid construct comprising a nucleic acid sequence further comprising a nucleic acid sequence encoding a other reporter protein that is secreted, a host cell or transgenic nonhuman animal comprising the nucleic acid encoding a nonelected reporter protein and method of using cell for *in vitro* or *in vivo* are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 3/23/2009.

Claims 1-8, 11-15, 19-27, 31-39 drawn to a nucleic acid construct comprising a nucleic acid sequence further comprising a nucleic acid sequence encoding a reporter protein that is secreted is a modified human beta choriogonadotrophin (hCG), a nonhuman animal and host cell comprising the nucleic acid and method of using cell for *in vitro* screening are under consideration.

Information Disclosure Statement

The IDS filed 3/22/2006 has been considered.

Specification

The disclosure is objected to because of the following informalities: The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See page 26, line 7.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Great Britain on 09/23/2003. It is noted, however, that applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b). Therefore, effective filing date of instant claim is 09/23/2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 11, 15, 19-27, 31-36 are rejected under 35 U.S.C. 102 (b) as being anticipated by Vogelstein et al (US Patent no 6419896 B1, dated 7/16/2002, IDS).

Claims are directed to a nucleic acid construct comprising a nucleic acid sequence further comprising a nucleic acid sequence encoding a reporter protein hCG that is secretable or excretable as a protein or product from a cell where the protein or product is expressed or produced. Dependent claims 2-6 limit the construct of 1, wherein the secretable/excretable protein or product is produced by modulated gene transcription, increased reporter translation, increased stability. It is noted that the limitation of claim 2-6 do not require any additional element that changes the composition of claim 1. Claims are also directed to a host cell, cell line and transgenic nonhuman animal comprising at least one nucleic acid construct of the invention (claim 1). Claims 31-33 are directed to methods that recite only one active step of assaying or evaluating the host cell, cell line or transgenic nonhuman animal. Claims 34-36 are directed to the nucleic acid construct of claim 1, wherein the reporter protein is expressed or produced in vitro or in vivo (nonhuman animal).

With respect to claim 1-6, 11, 15, Vogelstein et al teach a nucleic acid sequence comprising a nucleic acid sequence encoding a reporter protein hCG (human chorionic gonadotropin is a hormone) under the control of a promoter and where the protein or product is expressed or produced (see col2, lines 4-6, col. 4, lines 21, 53and claims 1). The term modified hCG set forth in the claim 11 does not indicate any specific modification that is required to practice the composition nor does it is expected to change in any characteristics of beta hCG. Thus, modified "a" hCG modified sequence is interpreted as any sequence that modifies hCG sequence in any way including one operbaly linked to a promoter that is disclosed by Vogelstein. Vogelstein teaches transcription control of reporter gene under a viral or metallothionein promoter control (col.4, lines 51-65). The nucleic acid construct disclosed by Vogelstein et al

and those embraced by the instant claims appear to be structurally same and therefore must necessarily be able to inherently perform functions set forth in claims 2-6. . Where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. Regarding claims 19-27, Vogelstein et al teach an isolated host cell (tumor cell) or tumor cells line comprises the expression construct that expresses the secretable protein (see col. 4, lines 25-27, 35-40) (limitation of claims 19-20) . Vogelstein et al also disclose a nonhuman animal comprising tumor cells that express the secretable exogenous marker protein, wherein the nonhuman animal is a mouse meeting the limitation of claim 21-23 (see col. 5, lines 10-15). It is also disclosed that the secreted /excreted protein is excreted in urine (see 5, lines 50-55) meeting the limitation of claims 24-25. Since, the host cell/ transgenic mouse comprising nucleic acid construct disclosed by Vogelstein et al and those embraced by the instant claims appear to be structurally same. Therefore, host cell must necessarily secrete reporter protein of ~60kd which is distinguishable from the endogenous molecule (limitation of claims 26-27). Where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. Regarding claims 31-33, Vogelstein teaches a method of monitoring xenograft of SW480 human colon carcinoma cells line derived cells that were genetically engineered and selected for expressing constructs of a reporter gene hCG (Abstract; col.8, lines 35-38; col.8, lines 45-59). Vogelstein teaches quantitative measurements of relationship between tumor burdens and urinary beta-hCG levels (col.5, lines 35-68; col.10, lines col. 9-10; col.4, lines 12-27, claim 1 of '896). Vogelstein teaches a post-transcriptional reporting mediated by reported excreted in urine and testing the effects therapeutic agents on various tumors (Abstract; col.10, lines col. 9-10; col.3, lines 1-40; col.6 lines 57-67 bridging col.7). Vogelstein et al also teaches recombinant clone of each line to further assay the secretable level of hCG meeting the limitations of claims 31-33. With respect to claims 34-36, the construct of Vogelstein et al is expressed or produced *in vitro* or *in vivo* (col. 4, lines 25-27, 35-40) or excreted from a nonhuman animal (see col. 5, lines 50-55).

Accordingly, Vogelstein et al anticipates claims 1-6, 11, 15, 19-27, 31-36.

Claims 1-6, 11, 15, 19-27 are rejected under 35 U.S.C. 102(a)/102 (b) as being anticipated by Matzuk et al (Biology of Reproduction, July 2003, 69, 338-346, online April 2003, IDS).

It is noted that the instant rejection is put forth because the Matzuk et al reference has 102(b) date availability due to the certified foreign priority document is not made of record. A certified English translation of the foreign priority document would remove the availability of the Matzuk et al reference under 102(b), if all the claimed subject matter were in fact disclosed in the foreign priority document. If it is determined that the claimed invention has priority in the foreign application 0322196.7 filed 9/23/2003, the rejection would be considered under 102(a).

With respect to claim 1-6, 11, 15, Matzuk et al teach a nucleic acid sequence comprising a nucleic acid sequence encoding a reporter protein hCG (human chorionic gonadotropin is a hormone) under the control of a mMT-1 promoter (see page 339, col.1, para. 3). The nucleic acid construct disclosed by Matzuk et al and those embraced by the instant claims appear to be structurally same and therefore must necessarily be able to inherently perform functions set forth in claims 2-6. Regarding claims 19, 21-27, Matzuk et al teach transgenic mouse and a host cell in mouse comprising the expression construct that expresses the secretable protein (see page 39, col.2, para.6 and table 1) (limitation of claims 19, 21-24) . Matzuk et al also teach the serum and urine level of hCG (table 1) meeting the limitation of claims 24-25. Since, the host cell/ transgenic mouse comprising nucleic acid construct disclosed by Matzuk et al and those embraced by the instant claims appear to be structurally same. Therefore, host cell must necessarily secrete reporter protein of ~60kd which is distinguishable from the endogenous molecule (limitation of claims 26-27).

Accordingly, Matzuk et al anticipates claims 1-6, 11, 15, 19-27.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 11, 13-15, 19-27, 31-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vogelstein et al (US Patent no 6419896 B1, dated 7/16/2002, IDS) and Beadet et al (WO/2000/079264, dated 12/28/2000, IDS).

Claims are directed to a nucleic acid construct comprising a nucleic acid sequence further comprising a nucleic acid sequence encoding a reporter protein hCG that is secretable or excretable as a protein or product from a cell where the protein or product is expressed or produced. In the instant case, modified hCG is interpreted to be modified by a peptide tag. Therefore, to address this interpretation, Vogelstein et al is used again in obviousness rejection.

With respect to claim 1-6, 11, 15, Vogelstein et al teach a nucleic acid sequence comprising a nucleic acid sequence encoding a reporter protein hCG (human chorionic gonadotropin is a hormone) under the control of a promoter and where the protein or product is expressed or produced (see col2, lines 4-6, col. 4, lines 21, 53and claims 1). Vogelstein teaches transcription control of reporter gene under a viral or metallothionein promoter control (col.4, lines 51-65). The nucleic acid construct disclosed by Vogelstein et al and those embraced by the instant claims appear to be structurally same and therefore must necessarily be able to implicitly perform functions set forth in claims 2-6. Regarding claims 19-27, Vogelstein et al teach an isolated host cell (tumor cell) or tumor cells line comprises the expression construct that expresses the secretable protein (see col. 4, lines 25-27, 35-40) (limitation of claims 19-20) . Vogelstein et al also disclose a nonhuman animal comprising tumor cells that express the secretable exogenous marker protein, wherein the nonhuman animal is a mouse meeting the limitation of claim 21-23 (see col. 5, lines 10-15). It is also disclosed the secreted /excreted protein is excreted in urine (see 5, lines 50-55) meeting the limitation of claims 24-25. Since, the host cell/ transgenic mouse comprising nucleic acid construct disclosed by Vogelstein et al and those embraced by the instant claims appear to be structurally same. Therefore, host cell must necessarily secrete reporter protein of ~60kd which is distinguishable from the endogenous molecule (limitation of claims 26-27). Where the claimed and prior art products are identical or substantially identical in structure or composition, a prima facie case of either anticipation or obviousness has been established. Regarding claims 31-33, Vogelstein teaches a method of

monitoring xenograft of SW480 human colon carcinoma cells line derived cells that were genetically engineered and selected for expressing constructs of a reporter gene hCG (Abstract; col.8, lines 35-38; col.8, lines 45-59). Vogelstein teaches quantitative measurements of relationship between tumor burdens and urinary beta-hCG levels (col.5, lines 35-68; col.10, lines col. 9-10; col.4, lines 12-27, claim 1 of '896). Vogelstein teaches a post-transcriptional reporting mediated by reported excreted in urine and testing the effects therapeutic agents on various tumors (Abstract; col.10, lines col. 9-10; col.3, lines 1-40; col.6 lines 57-67 bridging col.7). Vogelstein et al also teaches recombinant clone of each line to further assay the secretable level of hCG meeting the limitations of claims 31-33. With respect to claims 34-36, the construct of Vogelstein et al is expressed or produced *in vitro* or *in vivo* (col. 4, lines 25-27, 35-40) or excreted from a nonhuman animal (see col. 5, lines 50-55).

While Vogelstein et al describe the nucleic acid comprising a nucleic acid encoding a reporter protein, but differ from claimed invention by not disclosing wherein the construct further comprises a peptide tag or wherein hCG molecule is myc-tagged.

However, reporter gene containing an epitope tag that could be monitored under in vitro as well as in vivo condition was known and routine in the art. For instance, Beaudet et al teach the use of reporter proteins including human growth hormone with a peptide tag that are secreted into biological fluids and tissues, for instance blood and urine ((page 16, lines 18-page 17, line 10). It is noted that addition of peptide tag as additional mean for detection of a heterologous reporter protein in explicitly disclosed by Beaudet et al (see page 17, lines 1-4) meeting the limitation of claims 7, 8 and 37. Furthermore, Beaudet et al also teach that epitope tag may include HA, myc or Flag. It is relevant to point out that Beaudet et al disclose that in case of enzyme tags, colorimetric indicator substrates are known that can be employed to provide a detection means that is visibly or spectrophotometrically detectable, to identify specific hybridization with complementary nucleic acid containing samples (see page 32, lines 23-27). Regarding claims 8, 38 and 39, Beaudet et al teach a reporter system comprising a nucleic acid encoding two reporter protein under control of a promoter, wherein each reporter protein could be same or different (see example 7 and claims 1-4).

Therefore, it would have been *prima facie* obvious for a person of ordinary skill in the art seeking to develop a nucleic acid construct for the detection of gene activation events or

biochemical changes would combine the respective teachings of Vogelstein et al and Beaudet et al by modifying the reporter protein hCG disclosed by Vogelstein et al with known methods to myc tag as additional mean for detection of a heterologous reporter protein, with a reasonable expectation of success. A person of skill in the art would have been motivated to modify the reporter protein disclosed by Vogelstein et al with myc or other epitope tag as taught by Beaudet, as a matter of design choice, said design choice amounting to combining prior art elements according to known methods to yield predictable results. Given that Beaudet teaches addition of peptide tag as additional and alternative mean for detection of a heterologous reporter protein (supra), it would have been obvious for one of ordinary skill in the art to modify the hCG molecule disclosed by Vogelstein et al with myc or any other epitope tag. Other limitations of reporter system comprising two nucleic acid construct would have been also obvious in view of Beaudet et al who provided guidance to have multiple secreted proteins in a bicistronic marker (see example 7). One who would practiced the invention would have had reasonable expectation of success because Vogelstein et al had already described a nucleic acid construct comprising a nucleic acid further comprising a nucleic acid encoding a reporter protein hCG that is secretable or excretable. Beaudet et al teach the use of reporter proteins including human growth hormone with a myc tag that are secreted into biological fluids and tissues, for instance blood and urine, it would have only required routine experimentation to modify the construct of Vogelstein et al to with myc tag as taught by Beaudet. It should be noted that the *KSR* case forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness See the recent Board decision *Ex parte Smith*, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR*, 82 USPQ2d at 1396) (available at http: www. uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).

Thus, the claimed invention, as a whole, is clearly *prima facie* obvious in the absence of evidence to the contrary.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vogelstein et al (US Patent no 6419896 B1, dated 7/16/2002, IDS) and Beadet et al (WO/2000/079264, dated 12/28/2000, IDS) as applied to claims 1-8, 11, 13-15, 19-27, 31-39 above, and further in view of

Aprelikova et al (The Journal of Biological Chemistry, 2001, 276, 25647-25650) and Hermeking et al (Mol. Cell, 1997, 1, 3-11).

The combined teaching of Vogelstein et al and Beadet et al has been described above and relied in same manner. While combination of references teaches a nucleic acid construct comprising a nucleic acid sequence further comprising a nucleic acid sequence encoding a myc tagged reporter protein hCG that is secretable or excretable as a protein or product from a cell, but differ from claimed invention by not disclosing construct further comprising a stratifin gene promoter.

However, importance of 14-3-3s protein in cell transformation is suggested by the fact that 14-3-3sigma expression is silenced in the majority of cancers. It is noted that Aprelikova et al teach a nucleic acid construct comprising nucleic acid encoding reporter protein (luciferase) under the control of 14-3-3sigma promoter (stratifin promoter alternative name) (see page 25647, col. 2, para.4). Hermeking et al teach exogenous introduction of *14-3-3σ* into cycling cells results in a G2 arrest. It is noted that Hermeking et al teach he use of the stratifin promoter in combination with a reporter protein (figure 3). The promoter of the 14-3-3sigma gene is a marker of G2/M arrest occurring as a result of DNA damage and it is also transcriptionally upregulated via a p53-dependent mechanism during G2/M arrest in human tumor derived cell lines treatment with adriamycin, also known as doxorubicin (see figure 1).

Therefore, it would have been *prima facie* obvious for a person of ordinary skill in the art to combine the teachings of Vogelstein et al, Beadet et al and Aprelikova /Hermeking et al to modify the nucleic acid construct of Vogelstein et al, Beadet by substituting MT promoter disclosed by Vogelstein et al with another such as 14-3-3sigma promoter, as a matter of design choice, detection of a heterologous reporter protein, with a reasonable expectation of success, said design choice amounting to combining prior art elements according to known methods to yield predictable results. One of ordinary skill in the art would be motivated to use *14-3-3σ* promoter in order to study transcriptional activation of the SFN-hCG gene in response to chemotherapeutics such as adriamycin (supra). One who would practiced the invention would have had reasonable expectation of success because it was routine in the art at the time of filing to substitute one promoter taught by Vogelstein et al with another disclosed by Aprelikova et al / Hermeking, particularly since both had already shown that 14-3-3sigma promoter function well

in expression plasmids. It should be noted that the *KSR* case forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness See the recent Board decision *Ex parte Smith*, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing *KSR*, 82 USPQ2d at 1396) (available at http: www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. In the instant case, claims do not recite any method steps that positively link to preamble. As recite claims only require only one method steps comprising evaluating a cell, cell line or transgenic animal, but fails to set forth any step how and what is being monitored, characterized or activated. It is not clear how evaluation of a cell, cell line or animal would actually mean to the practicing of the method. Recitation of active method steps such as transfecting cell or cell line and then evaluating activation would obviate the basis of the rejection. Appropriate correction is required.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANOOP SINGH whose telephone number is (571)272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anoop Singh/
Examiner, Art Unit 1632